PATENT
ATTORNEY DOCKET 27866/32663

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of:	)	For: Methods for Using Agents that Bind to VCAM-1
Masinovsky *et al.*	)	
Serial No: 08/448,649	)	Group Art Unit: 1644
Filed: May 24, 1995	)	Examiner: P. Gambel, Ph.D.

APPELLANTS' REPLY BRIEF

Li-Hsien Rin-Laures, M.D.
Registration No. 33,547
MARSHALL, O'TOOLE, GERSTEIN,
MURRAY & BORUN
6300 Sears Tower
233 S. Wacker Drive
Chicago, IL 60606-6402
(312) 474-6300

December 11, 1998

REPLY BRIEF

A. Grouping of the Claims

The Examiner's apparent position that all claims stand or fall together is legally incorrect. The claims are not identical in either language or scope, and therefore the written descriptive support and enablement of each claim must be evaluated individually.

B. Written Description

1. A Rejection For Lack of Written Description Cannot Be Based on the Unrecited "Intent" or "Purpose" of the Claimed Methods

The Examiner has taken a legally incorrect position throughout the Answer that an unrecited "intent" or "purpose" of the claimed methods is somehow relevant to considerations of written descriptive support. See, for example, page 8, paragraphs 2-4 of the Answer, which state that "a key element and intent encompassed by the claimed methods" is blocking adhesion for the purpose of releasing hemopoietic cells from the bone marrow and that "there is insufficient written support for this key element of the claimed invention, drawn to methods . . . for the purpose of peripheralizing/mobilizing or harvesting hemopoietic stem and progenitor cells for bone marrow transplantation in the specification as filed." See also page 10, paragraph 3, discussing the "absence of a written description of peripheralizing or harvesting hemopoietic stem and progenitor cells by blocking VLA-4-expressing cell:VCAM stromal cell interactions" and page 9, paragraphs 4-5.

The Examiner appears to agree that Appellants were in possession of a use of anti-VCAM-1 antibody to decrease VCAM-1-mediated adhesion, but the Examiner's position is that Appellants contemplated blocking adhesion only for some select purposes and not for others. See, for example, page 9, paragraphs 4-5. The fatal flaw in this reasoning is that the claims do not state that the purpose of blocking adhesion is for peripheralizing/mobilizing or harvesting hemopoietic cells.

There is no statute or other authority requiring written descriptive support for language that does not appear in a claim. All that the claims recite is a "decrease [in] VCAM-1-mediated adhesion." To the extent that the rejection was based on a lack of written descriptive support for *unrecited elements,* such as peripheralizing/mobilizing or harvesting hemopoietic cells for bone marrow transplantation, the rejection was clearly erroneous and should be reversed.

The Examiner also erred by requiring Appellants' declaratory evidence to show written description in the specification for peripheralizing/mobilizing or harvesting hemopoietic cells. See page 9, paragraph 5 and page 10, paragraph 3. Dr. Torok-Storb's declaration (Exhibit D to Appellants' Brief) demonstrates that the specification conveys with reasonable clarity that anti-VCAM-1 antibodies are to be used for blocking adhesion between bone marrow stromal cells (which express VCAM-1) and any cell expressing VLA-4 (including lymphocytes and hemopoietic cells). This declaratory evidence was commensurate with the language in the claims; the Examiner's position that the declaration should have addressed other elements not recited in the claims was in error.

The rejection under 35 U.S.C. §112, first paragraph, for lack of written descriptive support should therefore be reversed with respect to all claims.

2. A Rejection For Lack of Written Description Cannot Be Based on Enablement Considerations such as "How to Use" the Claimed Methods

The Examiner has continued to improperly mix enablement and written description considerations. See, for example, the statement at page 8, paragraph 1 of the Answer that "*issues of 'how to use' have been relied upon* by the rejections of record, in part, to provide an explanation why the specification as filed *lacks adequate written support* for the claimed methods. (emphasis added)." Enablement considerations such as "how to use" cannot form the basis for a written description rejection because the written description and enablement requirements are "separate and distinct" requirements of 35 U.S.C. §112, first paragraph. *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For this reason, the rejection should be reversed with respect to all claims.

C. Enablement

1. A Rejection For Lack of Enablement Cannot Be Based On Written Description Considerations

The Examiner's Answer confirms that the enablement rejection was improperly based on the Examiner's collateral position on written description. For example, page 12, paragraph 5 of the Answer states that "neither the recitation of the claimed methods nor a discussion of causing the release of hemopoietic stem and progenitor cells finds *written support* in the specification as filed for the reasons above. *Therefore, the specification, in turn, does not provide guidance and direction*

to the claimed methods . . . (emphasis added)" As noted above, the written description and enablement requirements are entirely distinct issues, and one rejection cannot provide a basis for the other.

2. No Reasoning or Rebuttal Evidence was Provided to Explain Why Appellants' Declaratory Evidence Was Considered Non-Persuasive

Although the Examiner asserted that undue experimentation would be required to practice the claimed invention, the Examiner's Answer contains no analysis of the eight factors set forth in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which were addressed by Appellants in their initial brief. The Examiner simply reiterated the position (stated above with respect to written description) that the specification does not specifically recite and thus does not provide direction and guidance for peripheralizing/mobilizing or harvesting hemopoietic stem and progenitor cells.

As noted above, the claimed methods are directed to a "decrease [in] VCAM-1-mediated adhesion" and do not specifically recite peripheralizing/mobilizing hemopoietic cells. Nevertheless, Appellants presented declaratory evidence showing that the decrease in VCAM-1-mediated adhesion caused by *in vivo* administration of anti-VCAM-1 antibody does in fact result in mobilization of hemopoietic stem cells, as measured by counting hemopoietic colony forming units in peripheral blood samples. The declaratory evidence also demonstrated that one of ordinary skill in the art as of the August 2, 1990 effective filing date of the application would have been able to practice the claimed methods without undue experimentation. See paragraph 4 of Dr. Papayannopoulou's declaration (Exhibit F to Appellants' Brief).

The Examiner improperly disregarded the experimental evidence because it was post-filing, stating at page 13, paragraph 2 of the Answer that "the objective evidence of record indicates that the ability to mobilize hemopoietic cells with anti-VCAM antibodies was not determined until 1993, which is after appellant's priority date of 1990." However, the Examiner's position is legally incorrect because post-filing evidence may be considered when determining enablement as of the filing date. See *Gould v. Quigg*, 3 USPQ2d 1302, 1305 (Fed. Cir. 1987) (district court could "accept testimony of expert who had considered a later publication in the formulation of his opinion as to whether the disclosure was enabling as of the time of the filing date"); *In re Chilowsky*, 108 USPQ

321, 325 (CCPA 1956) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it"). Thus, in this case it was entirely proper for Dr. Papayannopoulou to consider post-filing experiments in formulating her opinion on enablement as of the application's priority date.

The Examiner's Answer did not identify any other alleged deficiencies in Appellants' declaratory evidence, nor did it explain why undue experimentation would have been involved in a simple procedure that consists of (1) giving a subject an intravenous injection of antibody, (2) taking a blood sample from the subject, and (3) counting the number of hemopoietic colony forming units in the blood sample, using techniques that were known long before the effective filing date of the application.

The enablement rejection under 35 U.S.C. §112, first paragraph, should therefore be reversed with respect to all claims.

Respectfully submitted,

MARSHALL, O'TOOLE, GERSTEIN,
MURRAY & BORUN

By 

Li-Hsien Rin-Laures, M.D.
Registration No. 33,547
Attorney for Appellants
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606-6402
(312) 474-6300

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